

Dear Mba Irene

Berikut hasil review CoA **Sulpiride** ex. Inner Mongolia Kangpu Pharmaceutical Co., Ltd. berdasarkan European Pharmacopoeia 11.0 sebagai berikut:

No	Parameter	EP 10	Spek CoA	Hasil CoA	Keterangan
1	Pemerian	Serbuk hablur atau kristal, putih atau hampir putih.	kristal, putih atau hampir putih.	Sesuai syarat	Sesuai dengan kompendial
2	Kelarutan	Praktis tidak larut dalam air; agak sukar larut dalam methanol; sukar larut dalam ethanol (96%) dan dalam methylene chloride; larut dalam larutan mineral asam dan alkali hidroksida	Praktis tidak larut dalam air; agak sukar larut dalam methanol; sukar larut dalam ethanol (96%) dan dalam methylene chloride; larut dalam larutan mineral asam dan alkali hidroksida	Sesuai syarat	Sesuai dengan kompendial
3	Identifikasi	A. Jarak lebur : 177°C - 181°C B. Spektrum serapan IR sampel menunjukkan respon yang sama seperti standar C. Bercak utama yang diperoleh dari larutan uji memiliki posisi dan ukuran yang sama dengan bercak utama dari larutan standar. D. Larutan menunjukkan flouresensi biru.	Spektrum serapan IR sampel menunjukkan respon yang sama seperti standar	Sesuai syarat	Berbeda dengan kompendial, pada CoA hanya tercantum identifikasi B (1 st identification), sedangkan identifikasi A, C dan D adalah 2 nd identification)
4	Kejernihan Larutan	Larutan jernih dan tidak lebih intensif dengan larutan reference Y6	Larutan jernih dan tidak lebih intensif dengan larutan reference Y6	Sesuai syarat	Sesuai dengan kompendial
5	Cemaran A	≤ 0.1%	≤ 0.1%	ND	Sesuai dengan kompendial
6	Senyawa Sejenis	Cemaran lain ≤ 0.1%	≤ 0.1%	ND	Sesuai dengan kompendial

		Total cemaran	$\leq$ 0.3%	$\leq$ 0.3%	ND	
7	Klorida	$\leq$ 100 ppm		$\leq$ 0.01%	Sesuai syarat	Sesuai dengan kompendial
8	Besi	$\leq$ 10 ppm		$\leq$ 0.001%	Sesuai syarat	Sesuai dengan kompendial
9	Susut Pengerinan	$\leq$ 0.5%		$\leq$ 0.5%	< 0.02%	Sesuai dengan kompendial
10	Sisa Pemijaran	$\leq$ 0.1%		$\leq$ 0.1%	< 0.1%	Sesuai dengan kompendial
11	Kadar	98.5 – 101.0%		98.5 – 101.0%	99.9%	Sesuai dengan kompendial
12	PSD	NA		D90 < 20 μ m	6.9 μ m	Parameter tidak tercantum di kompendial

Berdasarkan hasil review CoA tersebut, CoA telah sesuai dengan kompendial.

 11/8/25

Demikian disampaikan, terimakasih.

Salam,



Inner Mongolia Kangpu Pharmaceutical Co., Ltd.

ADD: Intersection East of No. 1 North Street and No.1 East Road, Development Test Zone of Transformation of Resource-dependent City of Chifeng, Yuanbaoshan District, Chifeng, Inner Mongolia, China.
Web: <https://nmkppy.com> Tel: +86476-5928168

质量检验报告

CERTIFICATE OF ANALYSIS

报告号/Report No: YC250710-01

生产日期/Manufacturing Date: 2025.06.30

产品名称/Product Name	舒必利/Sulpiride	包装/Packing	25kg/drum
批号/Lot. No	S2506003	数量/Quantity	470.8kg
检验项目/Test Items	全检/Full test	检验日期/Test Date	2025.07.10
检品来源/Sample From	原料药车间/API Workshop	报告日期/Report Date	2025.07.23
检验依据/Inspection Basis	EP 标准/EP 11.0	有效期至/Exp. Date	2029.06.29
项目/Test Item	接受标准/Specification	检验结果/Result	
性状/Appearance	白色或类白色结晶性粉末。几乎不溶于水，略溶于甲醇，微溶于乙醇（96%）和二氯甲烷。溶于矿物酸和碱氢氧化物的稀溶液。/White or almost white, crystalline powder; Practically insoluble in water, sparingly soluble in methanol, slightly soluble in ethanol (96 per cent) and in methylene chloride. It dissolves in dilute solutions of mineral acids and alkali hydroxides	符合规定/Complies	
鉴别/Identification	本品的红外光吸收图谱应与对照品的图谱一致。/The infrared absorption spectrum of the substance to be examined should be correspond to the spectrum of sulpiride CRS.	符合规定/Complies	
溶液澄清度/ Appearance of solution	溶液应澄清无色，或颜色不得浓于对照溶液 Y ₆ 。 The solution is clear, or not more intensely coloured than reference solution Y ₆ .	符合规定/Complies	
杂质 A / Impurity A	Not more than 0.1%	符合规定/Complies	
有关物质/Related Substances	未知杂质 / Unspecified impurities: ≤0.10%	未检出 / Not detected	
	总杂质 / Total: ≤0.3%	未检出 / Not detected	
残留溶剂/Residual solvent	乙醇/Ethanol ≤0.5%	0.04%	
	乙二醇/Ethylene glycol ≤0.062%	未检出 / Not detected	
	甲醇/Methanol ≤0.3%	0.0449%	
氯化物/Chlorides	不得过 0.01% / maximum 0.01 %	符合规定/Complies	
铁盐/Iron	不得过 0.001% / maximum 0.001 %	符合规定/Complies	
干燥失重/Loss on drying	不得过 0.5% / maximum 0.5 %	0.02%	
炽灼残渣/Sulfated ash	不得过 0.1% / maximum 0.1 %	<0.1%	
粒径/PSD	D90 < 20 μm	6.9 μm	
含量/Assay	98.5%~101.0% (按干燥品计/Calculated by dried substance)	99.9%	

结论：本品按 EP11.0 标准检验，结果符合规定。

Conclusion: The test results meet the requirements of EP 11.0.

检验人

Analyst 胡元 长

化验室负责人

QC supervisor 何明俊

质量部长

QA supervisor 林永志

Free sample
OK
10/10/25
EIT



Inner Mongolia Kangpu Pharmaceutical Co., Ltd.

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检品来源/Sample From	原料药车间/API Workshop	报告日期/Report Date	2025.07.23
检验依据/Inspection Basis	EP 标准/EP 11.0	有效期至/Exp. Date	2029.06.29
项目/Test Item	接受标准/Specification	检验结果/Result	
性状/Appearance	白色或类白色结晶性粉末。几乎不溶于水，略溶于甲醇，微溶于乙醇（96%）和二氯甲烷。溶于矿物酸和碱氢氧化物的稀溶液。/White or almost white, crystalline powder; Practically insoluble in water, sparingly soluble in methanol, slightly soluble in ethanol (96 per cent) and in methylene chloride. It dissolves in dilute solutions of mineral acids and alkali hydroxides	符合规定/Complies	
鉴别/Identification	本品的红外光吸收图谱应与对照品的图谱一致。/The infrared absorption spectrum of the substance to be examined should be correspond to the spectrum of sulpiride CRS.	符合规定/Complies	
溶液澄清度/ Appearance of solution	溶液应澄清无色，或颜色不得浓于对照溶液 Y ₆ 。 The solution is clear, or not more intensely coloured than reference solution Y ₆ .	符合规定/Complies	
杂质 A / Impurity A	Not more than 0.1%	符合规定/Complies	
有关物质/Related Substances	未知杂质 / Unspecified impurities: ≤0.10%	未检出 / Not detected	
	总杂质 / Total: ≤0.3%	未检出 / Not detected	
残留溶剂/Residual solvent	乙醇/Ethanol ≤0.5%	0.04%	
	乙二醇/Ethylene glycol ≤0.062%	未检出 / Not detected	
	甲醇/Methanol ≤0.3%	0.0449%	
氯化物/Chlorides	不得过 0.01% / maximum 0.01 %	符合规定/Complies	
铁盐/Iron	不得过 0.001% / maximum 0.001 %	符合规定/Complies	
干燥失重/Loss on drying	不得过 0.5% / maximum 0.5 %	0.02%	
炽灼残渣/Sulfated ash	不得过 0.1% / maximum 0.1 %	<0.1%	
粒径/PSD	D90 < 20μm	6.9μm	
含量/Assay	≥98.5%~101.0% (按干燥品计/Calculated by dried substance)	99.9%	

结论: 本品按 EP11.0 标准检验, 结果符合规定。

Conclusion: The test results meet the requirements of EP 11.0.

检验人

Analyst 石明江/张

化验室负责人

QC supervisor 张明

质量部长

QA supervisor 张明

System suitability: reference solution (b):

- resolution: minimum 2.0 between the peaks due to impurities C and B.

Calculation of percentage contents:

- correction factor: multiply the peak area of impurity C by 2;
- for each impurity, use the concentration of sulindac in reference solution (a).

Limits:

- impurity C: maximum 0.5 per cent;
- impurity B: maximum 0.4 per cent;
- impurity D: maximum 0.2 per cent;
- unspecified impurities: for each impurity, maximum 0.10 per cent;
- total: maximum 1.0 per cent;
- reporting threshold: 0.05 per cent.

Loss on drying (2.2.32): maximum 0.5 per cent, determined on 1.000 g by drying in an oven at 105 °C at a pressure not exceeding 0.7 kPa.

Sulfated ash (2.4.14): maximum 0.1 per cent, determined on 1.0 g.

ASSAY

Dissolve 0.300 g in 50 mL of *methanol R*. Titrate with 0.1 M sodium hydroxide, determining the end-point potentiometrically (2.2.20).

1 mL of 0.1 M sodium hydroxide is equivalent to 35.64 mg of $C_{20}H_{17}FO_3S$.

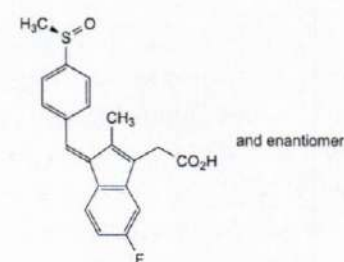
STORAGE

Protected from light.

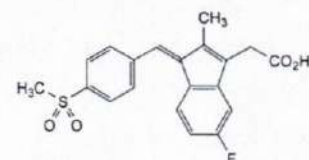
IMPURITIES

Specified impurities: B, C, D.

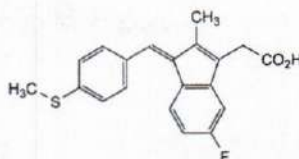
Other detectable impurities (the following substances would, if present at a sufficient level, be detected by one or other of the tests in the monograph. They are limited by the general acceptance criterion for other/unspecified impurities and/or by the general monograph *Substances for pharmaceutical use* (2034). It is therefore not necessary to identify these impurities for demonstration of compliance. See also 5.10. Control of impurities in substances for pharmaceutical use): A.



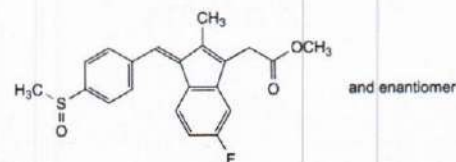
A. [(1E)-6-fluoro-3-[[4-[(RS)-methanesulfinyl]phenyl]methylidene]-2-methyl-3H-inden-1-yl]acetic acid,



B. [(1Z)-6-fluoro-3-[[4-(methanesulfonyl)phenyl]methylidene]-2-methyl-3H-inden-1-yl]acetic acid,



C. [(1Z)-6-fluoro-2-methyl-3-[[4-(methylsulfonyl)phenyl]methylidene]-3H-inden-1-yl]acetic acid,



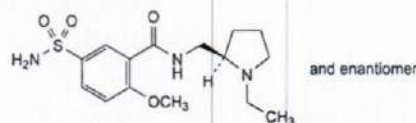
D. methyl [(1Z)-6-fluoro-3-[[4-[(RS)-methanesulfonyl]phenyl]methylidene]-2-methyl-3H-inden-1-yl]acetate.



01/2017:1045

SULPIRIDE

Sulpiridum



$C_{15}H_{23}N_3O_4S$
[15676-16-1]

M_r 341.4

DEFINITION

N-[[[(2RS)-1-Ethylpyrrolidin-2-yl]]methyl]-2-methoxy-5-sulfamoylbenzamide.

Content: 98.5 per cent to 101.0 per cent (dried substance).

CHARACTERS

Appearance: white or almost white, crystalline powder.

Solubility: practically insoluble in water, sparingly soluble in methanol, slightly soluble in ethanol (96 per cent) and in methylene chloride. It dissolves in dilute solutions of mineral acids and alkali hydroxides.

IDENTIFICATION

First identification: B.

Second identification: A, C, D.

A. Melting point (2.2.14): 177 °C to 181 °C.

B. Infrared absorption spectrophotometry (2.2.24).

Comparison: sulpiride CRS.

C. Examine the chromatograms obtained in the test for impurity A.

Detection: examine in ultraviolet light at 254 nm.

Results: the principal spot in the chromatogram obtained with test solution (b) is similar in position and size to the principal spot in the chromatogram obtained with reference solution (a).

D. To about 1 mg in a porcelain dish, add 0.5 mL of sulfuric acid R and 0.05 mL of formaldehyde solution R. Examined in ultraviolet light at 365 nm, the solution shows blue fluorescence.

TESTS

Appearance of solution. The solution is clear (2.2.1) and not more intensely coloured than reference solution Y₆ (2.2.2, Method I).

Dissolve 1.0 g in dilute acetic acid R and dilute to 10 mL with the same acid.

Impurity A. Thin-layer chromatography (2.2.27).

Test solution (a). Dissolve 0.20 g of the substance to be examined in methanol R, sonicate until dissolution is complete and dilute to 10.0 mL with the same solvent.

Test solution (b). Dilute 1.0 mL of test solution (a) to 10.0 mL with methanol R.

Reference solution (a). Dissolve 20 mg of sulpiride CRS in methanol R and dilute to 10.0 mL with the same solvent.

Reference solution (b). Dissolve 5.0 mg of sulpiride impurity A CRS in methanol R and dilute to 25.0 mL with the same solvent. Dilute 1.0 mL of the solution to 10.0 mL with methanol R.

Plate: TLC silica gel F₂₅₄ plate R.

Mobile phase: concentrated ammonia R, dioxan R, methanol R, methylene chloride R (2:10:14:90 V/V/V/V).

Application: 10 µL.

Development: over 1/2 of the plate.

Drying: in air.

Detection: examine in ultraviolet light at 254 nm for identification test C and then spray with ninhydrin solution R; heat at 100–105 °C for 15 min and examine in daylight.

Limit: test solution (a):

- **impurity A:** any spot due to impurity A is not more intense than the corresponding spot in the chromatogram obtained with reference solution (b) (0.1 per cent).

Related substances. Liquid chromatography (2.2.29).

Test solution. Dissolve 0.100 g of the substance to be examined in the mobile phase and dilute to 100.0 mL with the mobile phase.

Reference solution (a). Dilute 1.0 mL of the test solution to 100.0 mL with the mobile phase. Dilute 1.0 mL of this solution to 10.0 mL with the mobile phase.

Reference solution (b). Dissolve 5 mg of the substance to be examined and 5 mg of sulpiride impurity B CRS in the mobile phase and dilute to 50.0 mL with the mobile phase.

Column:

- **size:** $l = 0.25$ m, $\varnothing = 4.6$ mm;
- **stationary phase:** end-capped octylsilyl silica gel for chromatography R (5 µm).

Mobile phase: mix 10 volumes of acetonitrile R, 10 volumes of methanol R and 80 volumes of a solution containing 6.8 g/L of potassium dihydrogen phosphate R and 1 g/L of sodium octanesulfonate R, previously adjusted to pH 3.3 with phosphoric acid R.

Flow rate: 1.5 mL/min.

Detection: spectrophotometer at 240 nm.

Injection: 10 µL.

Run time: twice the retention time of sulpiride.

Identification of impurities: use the chromatogram obtained with reference solution (b) to identify the peak due to impurity B.

Relative retention with reference to sulpiride (retention time = about 15 min): impurity B = about 0.7.

System suitability: reference solution (b):

- **resolution:** minimum 2.5 between the peaks due to impurity B and sulpiride.

Calculation of percentage contents:

- for each impurity, use the concentration of sulpiride in reference solution (a).

Limits:

- **unspecified impurities:** for each impurity, maximum 0.10 per cent;
- **total:** maximum 0.3 per cent;
- **reporting threshold:** 0.05 per cent.

Chlorides (2.4.4): maximum 100 ppm.

Shake 1.0 g with 20 mL of water R. Filter through a sintered-glass filter (40) (2.1.2). To 10 mL of the filtrate add 5 mL of water R.

Iron (2.4.9): maximum 10 ppm.

Ignite 1.0 g in a silica crucible. To the residue add 1 mL of 1 M hydrochloric acid, 3 mL of water R and 0.1 mL of nitric acid R. Heat on a water-bath for about 5 min. Place the solution in a test-tube. Rinse the crucible with 4 mL of water R. Collect the rinsings in the test-tube and dilute to 10 mL with water R.

Loss on drying (2.2.32): maximum 0.5 per cent, determined on 1.000 g by drying in an oven at 105 °C.

Sulfated ash (2.4.14): maximum 0.1 per cent, determined on 1.0 g.

ASSAY

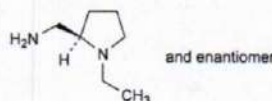
Dissolve 0.250 g in 80 mL of anhydrous acetic acid R. Titrate with 0.1 M perchloric acid, determining the end-point potentiometrically (2.2.20).

1 mL of 0.1 M perchloric acid is equivalent to 34.14 mg of C₁₅H₂₃N₃O₄S.

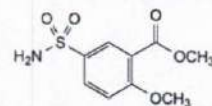
IMPURITIES

Specified impurities: A.

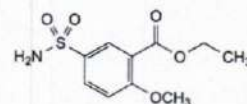
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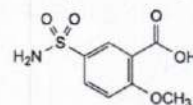
A. [(2RS)-1-ethylpyrrolidin-2-yl]methanamine,



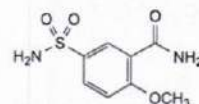
B. methyl 2-methoxy-5-sulfamoylbenzoate,



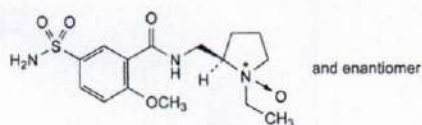
C. ethyl 2-methoxy-5-sulfamoylbenzoate,



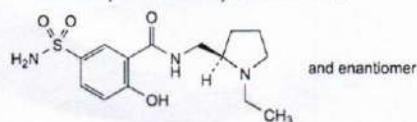
D. 2-methoxy-5-sulfamoylbenzoic acid,



E. 2-methoxy-5-sulfamoylbenzamide,



F. N-[[[(2RS)-1-ethyl-1-oxidopyrrolidin-2-yl]methyl]-2-methoxy-5-sulfamoylbenzamide,

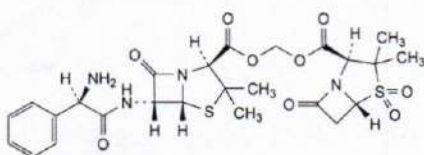


G. N-[[[(2RS)-1-ethylpyrrolidin-2-yl]methyl]-2-hydroxy-5-sulfamoylbenzamide.

01/2017:2211
corrected 11.0

SULTAMICILLIN

Sultamicillinum

C₂₅H₃₀N₄O₉S₂
[76497-13-7]

M, 594.7

DEFINITION

Methylene (2*S*,5*R*,6*R*)-6-[[[(2*R*)-aminophenylacetyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate (2*S*,5*R*)-3,3-dimethyl-4,4,7-trioxo-4λ⁶-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate.

Semi-synthetic product derived from a fermentation product.
Content: 96.0 per cent to 102.0 per cent (anhydrous substance).

CHARACTERS

Appearance: white or almost white, slightly hygroscopic, crystalline powder.

Solubility: practically insoluble in water, very slightly soluble in methanol, practically insoluble in ethanol (96 per cent).

IDENTIFICATION

Infrared absorption spectrophotometry (2.2.24).

Comparison: sultamicillin CRS.

TESTS

Specific optical rotation (2.2.7): + 190 to + 210 (anhydrous substance).

Dissolve 0.500 g in dimethylformamide R and dilute to 50.0 mL with the same solvent.

Related substances. Liquid chromatography (2.2.29). Prepare the solutions immediately before use or keep at 2–8 °C for not more than 6 h.

Solution A: methanol R1, acetonitrile R1 (20:80 V/V).

Solution B. Dissolve 1.56 g of sodium dihydrogen phosphate R in 900 mL of water R. Add 7.0 mL of phosphoric acid R and dilute to 1000 mL with water R.

Blank solution: solution B, solution A (30:70 V/V).

Test solution. Dissolve 50.0 mg of the substance to be examined in 35 mL of solution A and sonicate for about 1 min. Add 13 mL of solution B, mix and sonicate for about 1 min. Dilute to 50.0 mL with solution B and mix.

Reference solution (a). Dissolve 70.0 mg of sultamicillin tosilate CRS in 35 mL of solution A and sonicate for about 1 min. Add 13 mL of solution B, mix and sonicate for about 1 min. Dilute to 50.0 mL with solution B and mix.

Reference solution (b). Suspend 15 mg of sultamicillin tosilate CRS in 20 mL of a 0.4 g/L solution of sodium hydroxide R and sonicate in an ultrasonic bath for about 5 min. Add 20 mL of a 0.36 g/L solution of hydrochloric acid R and dilute to 100 mL with water R.

Reference solution (c). Dilute 1.0 mL of reference solution (a) to 100.0 mL with the blank solution.

Reference solution (d). Dissolve 17.3 mg of ampicillin trihydrate CRS (impurity C) and 15.0 mg of sulbactam CRS (impurity A) in water R and dilute to 50.0 mL with the same solvent. Dilute 1.0 mL of this solution to 100.0 mL with water R.

Reference solution (e). Dissolve 5 mg of sultamicillin for peak identification CRS (containing impurity G) in 7.0 mL of solution A and sonicate for about 1 min. Dilute to 10.0 mL with solution B, mix and sonicate for about 1 min.

Column:

- size: $l = 0.10$ m, $\varnothing = 4.6$ mm;
- stationary phase: octadecylsilyl silica gel for chromatography R (3.5 μ m);
- temperature: 25 °C.

Mobile phase:

- mobile phase A: 4.68 g/L solution of sodium dihydrogen phosphate R adjusted to pH 3.0 with phosphoric acid R;
- mobile phase B: acetonitrile R1;

Time (min)	Mobile phase A (per cent V/V)	Mobile phase B (per cent V/V)
0 - 15	95 → 30	5 → 70
15 - 16	30	70
16 - 16.5	30 → 95	70 → 5
16.5 - 20	95	5

Flow rate: 1.0 mL/min.

Detection: spectrophotometer at 215 nm.

Injection: 5 μ L of the blank solution, the test solution and reference solutions (b), (c), (d) and (e).

Identification of impurities: use the chromatogram supplied with sultamicillin for peak identification CRS and the chromatogram obtained with reference solution (e) to identify the peak due to impurity G.

Relative retention with reference to sultamicillin (retention time = about 9.3 min): impurity A = about 0.41; ampicillin penicilloic acid = about 0.47; impurity B = about 0.50; impurity C = about 0.55; impurity D = about 0.94; impurity E = about 1.09; impurity F = about 1.26; impurity G = about 1.42.

System suitability: reference solution (b):

- resolution: minimum 2.5 between the peaks due to ampicillin penicilloic acid and impurity B and minimum 2.5 between the peaks due to impurities B and C.

Limits:

- impurity G: not more than the area of the peak due to sultamicillin in the chromatogram obtained with reference solution (c) (1.0 per cent);
- impurity A: not more than the area of the corresponding peak in the chromatogram obtained with reference solution (d) (0.3 per cent);
- impurity B: not more than the area of the corresponding peak in the chromatogram obtained with reference solution (c) (0.3 per cent);
- impurity C: not more than the area of the corresponding peak in the chromatogram obtained with reference solution (d) (0.3 per cent);